

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: David B. Volkin et al.

Serial No. to be assigned

Filed:

For: POLYNUCLEOTIDE VACCINE FORMULATIONS

Art Unit: 1632

Examiner: Anne Marie Sabina  
Wehbe

Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

Sir:

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3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to the waiver by the Office of the requirement under 37 CFR 1.98 (a)(2)(i) dated July 11, 2003, if the filing date of this application is after June 30, 2003, copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

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MERCK &amp; CO., INC.

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## INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
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6. In accordance with 37 C.F.R. 1.97, (check one)

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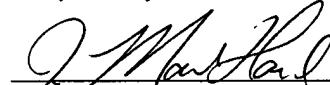
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Respectfully submitted,



By: J. Mark Hand

Attorney \_\_\_\_\_ For Applicant(s)

Reg. No. 36,545

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Patent Dept., RY60-30

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Substitute for Form 1449A/PTO  
**INFORMATION DISCLOSURE**  
**STATEMENT BY APPLICANT**

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**COMPLETE IF KNOWN**

<b>Application Number</b>	
<b>Filing Date</b>	
<b>First Named Inventor</b>	D. Volkin
<b>Group Art Unit</b>	1632
<b>Examiner Name</b>	Anne Marie Sabrina Wehbe
<b>Attorney Docket Number</b>	19907YIACB

## U.S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

Examiner Signature \_\_\_\_\_ Date Considered \_\_\_\_\_

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Group Art Unit	1632		
Examiner Name	Anne Marie Sabrina Wehbe		
Sheet	2	of	3
			Attorney Docket Number
			19907YIACB

**OTHER NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
A	Haynes et al. 'Update on the Issues of HIV Vaccine Development', Ann Med. Vol 28, pp 39-41, 1996	
B	Chiang et al. 'Research and Development of Adjuvants for Cell Culture Derived Japanese Encephalitis Vaccine', J. of Microbiology Immunology and Infection, Vol 31, No. 1, pp 58-63, 1998	
C	Hem et al. 'Accessibility of Antigen in Vaccines Prouded by in Situ Alum Precipitation', Vaccine Research, Vol 5, No. pp 187-191, 1996	
D	Brubaker et al. 'Th1-Associated Immune Responses...Replication Defective Herpes Simplex Virus', J. of Immunology, Vo.. 157, No. 4 pp 1598-1604, 1996	
E	Rinella et al. 'Elutability of Proteins from Aluminum-Containing Vaccine Adjuvants by Treatment with Surfactants', J. of Colloid and Interface Science, Vol. 197, No. 1 pp 48-56, 1998	
F	York et al. 'Immunomodulatory effects of HSV2...for immunotherapy of recurrent HSV infection', Vaccine, Vol. 13, No. 17, pp 1706-1712, 1995	
G	McClements et al. 'Immunization with DNA vaccines...herpes simplex virus-2 disease' Proc. Natl. Acad. Sci., Vol. 93, pp 11414-11420, 1998	
H	Manickan et al. 'Genetic Immunization Against Herpes Simplex Virus', J. of Immunology, Vol 155, NO. 1 pp. 259-265, 1995	
I	Berman et al. 'Protection from Genital Herpes Simplex Virus Type 1...Glycoprotein D', Science, Vol 227, pp 1490-1492 1985	
J	York et al. 'Immunomodulatory effects of HSV... HSV infection', Vaccine, Vol 13, pp 1706-1712, 1998	
K	Ross et al. 'Gene Therapy in the United States: A five-year Status Report', Human Gene Therapy, Vol 7, pp 1781-1790, 1996	
L	Dropulic et al. 'Gene Therapy for Human Immunodeficiency Virus Infection: Genetic Antiviral Strategies and Targets for Intervention', Human Gene Therapy, Vol. 5 pp 927-939, 1994	
M	Essex et al. 'Gene Therapy Against Retroviral Diseases', Leukemia, Vol. 9 Suppl. 1, S71-S74, 1995	
N	Durrani et al. 'Intranasal immunization with a plant virus...than oral immunization', J. of Immunological Methods, Vol. 220, pp 93-103, 1998	
O	Miller et al. 'Targeted vectors for gene therapy', FASEB J. Vol. 9, pp 109-199, 1995	

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**Application Number**

**Filing Date**

**First Named Inventor**

D. Volkin

**Group Art Unit**

1632

**Examiner Name**

Anne Marie Sabrina Wehbe

**Attorney Docket Number**

19907YIACB

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
P		Crystal et al. 'Transfer of Genes to Humans: Early Lessons and Obstacles to Cussess', Science Vol. 270, pp 404-410, 1995
Q		Deonarain, 'Ligand-targeted receptor-mediated vectors for gene delivery', exp. Opin. Ther. Patents, Vol. 8 pp 53-69, 1998
R		Verma et al. 'Gene Therapy-promises, problems and prospects', Nature, Vol. 389, pp 239-242, 1997
S		Orkin et al., 'Reports and Recommendations fo the Panel...on Gene Therapy', NIH Report and Recommendations 1995
T		Frynan et al. 'DNA Vaccines: protective imminizations by parenteral, mucosal and gene gun inoculations', Proc. Nat. Acad. of Sci., Vol. 90, pp11478-11482, 1993
U		Ulmer et al. 'Toward the development of DNA vaccines', Current Opinion in Biotechnology, Vol. 7, No. 6, pp 653-568, 1996
V		Benevisty et al. 'Direct Introduction of genes into rates and expression of the genes', Proceedings of the National Academy of Sciences, USA, Vol. 83, No. 24, pp 9551-9555, 1986
W		Gupta et al. 'Adjuvants for human vaccines - current status, problems and future prospects', Vaccine, Vol. 13, No. 14, p 1269, 1995
X		Yasutomi et al., 'A Vaccine-Elicited, Single Viral Epitope-Specific Tytotoxic T...Immunodeficiency Virus Challenge', Journal of Virology, pp 2279-2284, 1995
Y		Ertl et al. 'Genetic Immunizaiton', Viral Immunology, Vol 9, pp 1-9, 1996
Z		Monteil et al. 'Genetic immunization of seronegative one-day-old piglets...from immune dams', Genetic Immunization, Vol. 27, pp 443-452, 1996
AA		Golding et al.. 'The Potential for Recruiting Immune Responses Toward Type 1 or Type 2 Cell Help', American Society of Tropical medicine and Hygiene, pp 33-40, 1994
AB		Xiang et al. 'Vaccination with a Plasmid Vector Carrying the Rabies Virus Glycoprotein Gene Induces Protective Immunity against Rabies Virus', Virology, Vol. 199, pp 132-140, 1994
AC		Marshall, 'Gene Therapy's Growing Pains', Science, Vol. 269, pp 1050-1055, 1995
AD		Restifo et al. 'Molecular Mechanisms Used by Tumors to Escape Immune Recognition:... Complex Class I', Journal of Immunology, Vol. 14, pp 182-190, 1993

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